

EPA's Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products

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1 Executive Summary

Today, EPA is proposing additional mandatory pesticide label restrictions to protect managed bees under contract pollination services from foliar applications of pesticides that are acutely toxic to bees on a contact exposure basis. These restrictions would prohibit applications of pesticide products, which are acutely toxic to bees, during bloom where bees are known to be present under contract; these restrictions will apply to most insecticides and some herbicides. Today's proposed requirements would not supersede existing, more restrictive product use specifications.

EPA is also encouraging the efforts currently made by states and tribes to reduce pesticide exposures through development of locally-based measures. Specifically, EPA has been working with its state and tribal partners to develop Managed Pollinator Protection Plans (MP³s). Such plans were discussed in the June 2014, Presidential Memorandum¹ (the Memorandum or directive) and the National Strategy to Promote the Health of Honey Bees and Other Pollinators² (the Strategy) which identifies public/private partnerships as one means of addressing pollinator declines. These MP³s would include local and customizable mitigation measures to address certain scenarios that can result in exposure to pollinators. EPA will monitor the success of these plans in deciding whether further label restrictions are warranted.

Today's proposal addresses only acute exposure to pesticides from foliar applications under specific conditions. While the proposed mitigation focuses on managed bees under contract pollination services, EPA believes that in protecting managed bees in these circumstance, these measures would also protect native solitary and social bees that are also in and around treatment areas. Moreover, EPA recognizes there are concerns associated with potential exposure to chemicals that are not classified as acutely toxic by contact, including chemicals used in combination which may result in enhanced toxicity, and crops which incorporate pesticide residues in pollen/nectar. Future EPA actions will address these situations. EPA will continue to conduct chemical-specific risk assessments for bees and will consider additional product-specific mitigation as needed in the Office of Pesticide Program's (OPP's) registration and registration review programs.

Today's proposal, as well as EPA's support for development of state and tribal MP³s, is consistent with the President's directive and the National Strategy to Promote the Health of Honey Bees and Other Pollinators, which addresses the multiple factors affecting honey bees and pollinator health. The Strategy explains the need to expand federal efforts to reverse pollinator losses and calls for the development of new public-private partnerships across various sectors (state, tribal and local governments, industry, and non-governmental organizations) to reverse pollinator losses and restore populations to healthy levels.

¹ White House. 2014. Presidential Memorandum Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators. Memorandum for Heads of Executive Departments and Agencies. June 20, 2014. <http://www.whitehouse.gov/the-press-office/2014/06/20/presidential-memorandum-creating-federal-strategy-promote-health-honey-b>

² White House. 2015. National Strategy to Promote the Health of Honey Bees and Other Pollinators. May 19, 2015. <https://www.whitehouse.gov/sites/default/files/microsites/ostp/Pollinator%20Health%20Strategy%202015.pdf>

2 Background

EPA has taken steps, starting with the development of improved scientific tools to assess risks, to manage potential risks from pesticides to pollinators. EPA has routinely required toxicity tests with honey bees and has used these data as a surrogate for assessing risks to terrestrial invertebrates in general. In recent years there has been increasing uncertainty regarding whether these acute toxicity data are adequate to evaluate the role that pesticides play in pollinator declines. Consequently, EPA began to explore whether a broader suite of studies was needed to evaluate potential risks to bees. In response, EPA, Health Canada's Pest Management Regulatory Agency (PMRA), and the California Department of Pesticide Regulation (CDPR) developed a harmonized risk assessment framework that was presented to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) in 2012³. After considering the SAP's advice, the EPA now has formalized its scientific process for quantifying potential risks to bees⁴. Data required for the risk assessment framework informs EPA risk assessors of the potential for adverse effects to individual bees, as well as bee colonies, from exposure that may result from the labeled use of a pesticide. This framework is now an integral part of the registration and registration review programs. Laboratory and field-based tests are also being developed for additional species of solitary and social bees^{5 6}.

Pesticide labels have routinely included bee advisory statements as outlined in 40 CFR 156.85(b)(5)⁷ and the Label Review Manual⁸ based on data from acute contact toxicity tests (*e.g.*, OCSPP Guideline 850.3020⁹) and studies on the toxicity of residues on foliage (OCSPP Test Guideline 850.3030¹⁰) using honey bees. The Directions for Use sections of the label of some products have also included more specific restrictions to protect pollinators, based on EPA's analysis of potential exposure and effects of the particular pesticide. However, stakeholders have continued to emphasize the need for greater clarity and stronger protections^{11 12}.

³ USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11 – 14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation http://www.epa.gov/oppfeed1/cb/csb_page/updates/2012/sapmtg-sept.html

⁴USEPA. 2014a. Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

⁵ ICP-PR. 2012. Proceedings of the 11th International Symposium on the International Commission for Plant-Pollinator Relationships (ICP-PR) Bee Protection Group. Wageningen, Netherlands, November 2 – 4, 2011. Published in P.A. Oomen and H. Thompson eds, Julius Kühn Archiv 437.

⁶ ICP-PR. Proceedings of the International Commission for Plant-Pollinator Relationships (ICP-PR) Bee Protection Group 12th International Symposium Hazards on Pesticides to Bees. Ghent, Belgium. September 15 – 17, 2014. In preparation

⁷ CFR. 2014. Code of Federal Regulations. Title 40 (Protection of Environment), Chapter 1 (Environmental Protection Agency) Subchapter E (Pesticide Programs) Part 156 (Labeling Requirements for Pesticides and Devices) Subpart E (Environmental Hazard and Precautionary Statements) §156.85 (Non-target organisms) http://www.ecfr.gov/cgi-bin/text-idx?SID=511673be0c81c693acae95773c696225&node=se40.24.156_185&rgn=div8

⁸ USEPA. 2012. Label Review Manual. <http://www.epa.gov/oppfeed1/labeling/lrm/>

⁹ USEPA. 2012a. Ecological Effects Test Guidelines. OCSPP 850.3020 Honey Bee Acute Contact Toxicity. EPA 712-C-019. January 2012. http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series850.htm

¹⁰ USEPA. 2012b. Ecological Effects Test Guidelines OCSPP 850.3030 Honey Bee Toxicity of Residues on Foliage. EPA 712-C-018. January 2012. http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series850.htm

¹¹ USDA. 2013b. Report on the National Stakeholders Conference on Honey Bee Health. National Honey Bee Health Stakeholder Conference Steering Committee. October 17 – 17, 2012. <http://www.usda.gov/documents/ReportHoneyBeeHealth.pdf>

¹² *Ibid* USEPA 2014b

In August 2013, EPA developed new label language for certain neonicotinoid insecticides¹³ in response to concerns from various stakeholder groups that these compounds represented a particular hazard to managed bees. At that time, EPA recognized that different exposure scenarios following foliar applications of the neonicotinoid pesticides warranted different degrees of mitigation. In one scenario (Scenario 1), large numbers of managed bees may be directly exposed to pesticide spray because they have been intentionally placed within or adjacent to the area being treated (*i.e.*, under a contract to pollinate a crop). In a second scenario (Scenario 2), managed bees may be directly exposed to pesticide spray via off-site pesticide drift, or because the bees are within forage range of the application area.

The label language developed¹⁴ for the neonicotinoid pesticides reflected the likelihood of different exposures for managed bees in Scenario 1 and Scenario 2. Given the intentional placement of colonies into or adjacent to the application area, the managed bees under contract pollination services (Scenario 1) are nearly certain to be exposed if an application is made. Consequently, to protect managed bees under contract pollination services at the application site, EPA prohibited application of neonicotinoid products while bees are foraging and until flowering is complete with the single exception of 48-hour notification to the beekeepers prior to foliar applications. For managed bees not under contract pollination services (Scenario 2), EPA prohibited application while bees are foraging and until flowering is complete but with more exceptions to enable growers and beekeepers to reduce potential exposure to bees while affording growers some flexibility to apply pesticides for crop protection. EPA concluded, consistent with the statutory mandate under FIFRA¹⁵, that these modifications of the neonicotinoid labels reduced the risks to bees in a manner that improved the overall balance of risks and benefits from using these pesticides.

Following issuance of the August 2013 letter¹⁶ directing label changes for neonicotinoid products, EPA announced its intention to follow a similar approach with other pesticides that are applied to the foliar surfaces of plants and are acutely toxic to bees on contact, *i.e.*, those pesticides with an acutely lethal dose to 50% of the bees tested (abbreviated LD₅₀) of less than 11 micrograms per bee (<11 µg/bee), based on either the acute contact toxicity test following OCSPP Guideline 850.3020¹⁷ or its equivalent test in Europe (*i.e.*, OECD 214¹⁸). These acute toxicity data, which have been routinely required for pesticides, are frequently corroborated with bee kill incident data reported to EPA. The use of incident

¹³ Neonicotinoids are a class of insecticides with a common mode of action that affects the central nervous system of insects, causing paralysis and death.

¹⁴ USEPA. 2014c. New Labeling for Neonicotinoid Pesticides. <http://www2.epa.gov/pollinator-protection/new-labeling-neonicotinoid-pesticides>

¹⁵ The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides federal control of pesticide distribution, sale and use. All pesticides used in the United States must be registered (licensed) by EPA. For more information, see: <http://www.epa.gov/agriculture/lfra.html>

¹⁶ USEPA. 2013c. Memorandum to Registrants of Neonicotinoid Products on Pollinator Protection Labeling for nitroguanidine neonicotinoid products. <http://www2.epa.gov/sites/production/files/2013-11/documents/bee-label-info-ltr.pdf>

¹⁷ *Ibid* USEPA. 2012a.

¹⁸ OECD. 1998. OECD Guidelines for the Testing of Chemicals. Test Number 214, Acute Contact Toxicity Test. http://www.oecd-ilibrary.org/environment/test-no-214-honey-bees-acute-contact-toxicity-test_9789264070189-en;jsessionid=43gvto47wnue9.delta

data as a line of evidence in evaluating the potential risks associated with pesticides is discussed in associated guidance documents^{19 20 21 22}.

3 Problem Statement

Pesticides, particularly those intended to control insect pests, can harm bees. Pesticides have also been identified as one among multiple factors negatively impacting pollinator health, including declines in honey bees specifically^{23 24}. Through discussions with various stakeholders and based on reported bee kill incidents contained within the EPA Incident Data System (IDS) and the Ecological Incident Information System (EIIIS) databases for a large number of pesticides that have been classified as moderately or highly toxic to bees on an acute exposure basis, EPA has concluded that additional measures would provide better protection for bees from acute contact exposures. EPA is also aware that there are often inadequate relationships and a lack of suitable communication mechanisms in place at the local level between and among beekeepers, growers, and pesticide applicators to assure that pesticides needed to protect crops can be applied in ways that are not harmful to bees. Therefore, clearer and more consistent mandatory label restrictions could reduce the potential exposure to bees from pesticides categorized as acutely toxic to bees, *i.e.*, those compounds with an acute contact LD₅₀<11 µg/bee, in situations where large numbers of managed bees are intentionally positioned under contract in or close to pesticide application sites. In addition, EPA believes that state and tribal managed pollinator protection plans provide a means of developing localized and customized mitigation measures to reduce exposure of bees to pesticides in certain scenarios.

4 Desired State

A common theme from discussions about pesticides and pollinators with one of EPA's federal advisory committees, the Pesticide Program Dialogue Committee (PPDC)²⁵, and with other stakeholder groups²⁶ has been the need for clearer communications between growers/applicators, beekeepers and enforcement authorities. Stakeholders have indicated that more direct lines of communication are

¹⁹ USEPA 2011. Memorandum from Donald J. Brady, Director on Guidance for Using Incident Data in Evaluating Listed and Non-listed Species under Registration Review. http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/terrestrial_biology_tech_team/honeybee_data_interim_guidance.pdf

²⁰ *Ibid* USEPA 2004

²¹ *Ibid* USEPA 2012

²² *Ibid* USEPA 2014a

²³ *Ibid* USDA 2013

²⁴ vanEngelsdorp, D., J. D. Evans, C. Saegerman, C. Mullin, E. Haubruge, B. K. Nguyen, M. Frazier, J. Frazier, D. Cox-Foster, Y. Chen, R. Underwood, D. R. Tarpy, J. S. Pettis. 2009. Colony Collapse Disorder: A Descriptive Study. PLoS ONE 4(8): e6481.

Doi:10.1371/journal.pone.0006481 <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0006481>

²⁵ A description of the USEPA Pesticide Program Dialogue Committee Pollinator Protection Workgroup can be found at <http://www2.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee>

²⁶ *Ibid* USDA. 2013b.

needed at the local level. Groups such as the State FIFRA Issues Research and Evaluation Group (SFIREG²⁷) have echoed these concerns.

As directed by the Presidential Memorandum and described in the Strategy, EPA is working with states and tribes to increase the communication among all local stakeholders that have a part in protecting bees from exposure to pesticides and to promote implementation of integrated pest management (IPM²⁸). The EPA sees collaboration on Managed Pollinator Protection Plans (MP³s) as a means to enhance communication and risk mitigation. The purpose of an MP³ with respect to pesticide use is to utilize local expertise to identify customizable solutions to effectively mitigate risk from acutely toxic pesticides to managed bees²⁹.

EPA is aware of concerns that approaches to assess and mitigate risk to managed honey bees may not be protective of unmanaged bees (*i.e.*, “native” or “wild” bees). EPA’s ecological risk assessment framework documents^{30 31 32}, discuss the uncertainties associated with the use of surrogate species (*e.g.*, the use of the honey bee) for determining the potential for adverse effects to untested insect pollinator species as a result of exposure to pesticides. Using the honey bee as a surrogate species is consistent with both its established use in risk assessment and the currently available science. EPA believes that the approach taken to protect managed honey bees will also decrease the risks to wild bees since pesticides are generally likely to affect wild bees and managed bees in a similar manner. Moreover, EPA believes that additional measures to protect managed bees will provide protections to other pollinators as well. For example, measures designed to ensure that applications are only made when managed bees are not likely to be foraging will also be effective for other pollinators with similar foraging behavior and will reduce potential exposure to wild bees as well. This effort is also consistent with the Presidential directive and the Strategy which seeks to promote the health of honey bees and other pollinators to “*ensure the sustainability of our food production systems, avoid additional economic impact on the agricultural sector and protect the health of the environment.*”³³

²⁷ The State FIFRA Issues Research and Evaluation Group (SFIREG) is comprised of State, Federal, Tribal and Association representatives, and meets periodically to identify and discuss issues related to pesticides that affect the states/tribes. A description of SFIREG can be found at the following link: <http://www.aapco.org/sfireg.html>

²⁸ Integrated Pest Management (IPM) programs use current, comprehensive information on the life cycles of pests and their interaction with the environment. This information in combination with available pest control methods, is used to manage pest damage by the most economical means while minimizing potential hazards to people, property and the environment.

²⁹ Managed bees include those for purposes of pollination services and honey production (*i.e.*, honey bees, bumble bees, alfalfa leaf cutters, and blue orchard bees). Managed bees may be managed by hobbyists or commercial beekeepers.

³⁰ *Ibid* USEPA 2004

³¹ *Ibid* USEPA 2012

³² *Ibid* USEPA 2014a

³³ *Ibid* White House. 2014

Over the last few years, several states, such as California³⁴ ³⁵, Colorado³⁶, Florida³⁷, Mississippi³⁸, North Dakota³⁹ and others, have independently developed state-specific pollinator protection plans to enhance communication between stakeholders (*e.g.*, beekeepers, growers, applicators) which in turn is intended to reduce the potential exposure to bees from pesticides. In some cases, states have completed rule-making (*e.g.*, Iowa⁴⁰ and California⁴¹) which has established mandatory mitigation measures where beekeepers must be notified in advance of applications or applications may not take place during times when bees are likely to be foraging on the treated crop. These states have developed these plans in response to the needs of the growers and beekeepers of their states. The plans are aimed at identifying measures to mitigate potential exposure to bees from pesticides while providing flexibility to growers and beekeepers. A common element of each of the plans has been that they are founded on stakeholder engagement and consensus building; therefore, the state pollinator plans foster communication and collaboration between growers and the beekeepers. Feedback from state lead agencies, which have developed pollinator protection plans, indicates that the plans have been effective in increasing communication and mitigating risk. This result is evident from decreased numbers of bee kill incident reports, an increase in the number of bee hives registered in apiary registries, and an increased number of requests for advice when landowners cannot reach beekeepers. Although there are areas of commonality in the state-specific plans, they take many different approaches, since each reflects local conditions and local solutions.

One element of the Strategy is for EPA to engage with states and tribes and others on the development of pollinator protection plans. EPA's initial discussions about pollinator protection plans have been with co-regulators through the SFIREG, the Association of American Pesticide Control Officials (AAPCO⁴²) and the Tribal Pesticide Program Council (TPPC). These discussions have led to the realization that additional guidance is needed for states and tribes in the development of such plans, and state lead agencies are developing such guidance. As discussed in section 5.3.1, a draft guidance document has been circulated for wider review by states and will be made available following incorporation of their feedback.

5 Proposed Mitigation Approach and Rationale

EPA is proposing label changes to provide additional protections to managed bees under contract pollination services and is encouraging local solutions in the form of state and tribal MP³s for managed

³⁴ California Department of Food and Agriculture. 2014. Bee and Beehive Information.

<http://www.cdffa.ca.gov/plant/PE/interiorexclusion/bees.html>

³⁵ California Food and Agricultural Code Section 29040-29056 <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=fac&group=29001-30000&file=29040-29056>

³⁶ Colorado Environmental Pesticide Education Program. Pollinator Protection 2013.

<http://www.cepep.colostate.edu/Pollinator%20Protection/index.html>

³⁷ Florida Department of Agriculture and Consumer Services. 2014. Florida Bee Protection. <http://www.freshfromflorida.com/Divisions-Offices/Agricultural-Environmental-Services/Consumer-Resources/Florida-Bee-Protection>

³⁸ Mississippi Honeybee Stewardship Program. 2014 http://www.msfb.org/public_policy/Resource%20pdfs/Bee%20Brochure.pdf

³⁹ North Dakota Department of Agriculture. 2014. North Dakota Pollinator Plan. A North Dakota Department of Agriculture Publication.

<http://www.nd.gov/ndda/files/resource/NorthDakotaPollinatorPlan2014.pdf>

⁴⁰ Iowa Department of Agriculture. Advancing Iowa's Agricultural Interests. See Iowa Administrative Code Chapter 21-45.31(206).

http://www.iowaagriculture.gov/horticulture_and_farmersmarkets/sensitivecropdirectory.asp

⁴¹ California Department of Pesticide Regulation. Food and Agriculture Code Section 29040-29056. <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=fac&group=29001-30000&file=29040-29056>

⁴² AAPCO. 2014. Association of American Pesticide Control Officials. <http://www.aapco.org/>

bees not under contract services. EPA will work with state and tribal lead agencies to facilitate adoption of and compliance with MP³s that reflect public stakeholder processes. EPA will monitor the success of these plans in mitigating risk to bees from acutely toxic pesticides on an ongoing basis and determine whether additional EPA action is warranted. In the following section, the scope of these changes is discussed.

5.1 General Approach

EPA continues to believe that bees are likely to be exposed from application of acutely toxic pesticides, although the certainty such exposure will occur differs in ways that warrant different approaches to risk mitigation. When managed bees are on site under contract to pollinate the crop, which can also be the application area, relatively large numbers of bees are intentionally placed in or near the crop area, *i.e.*, managed bees are a direct input to the production of the crop. Consequently, large numbers of bees are likely to be directly exposed to pesticide spray during a pesticide application. Underscoring the potential magnitude of colonies that may be present at an application site requiring contracted pollination services, the EIS database contains reports from commercial beekeepers of adverse effects to roughly 20,000 colonies contracted to support pollination services in almonds and roughly 2,000 colonies contracted to support pollination services in blueberries purportedly due to pesticide applications made while large numbers of colonies were in or near treatment areas in 2014 alone. In addition, EPA has heard claims of tens of thousands more colonies in almonds and blueberries being affected in 2014. (EPA notes, however, that it is not clear whether these adverse effects were acute or chronic with respect to the timing of pesticide applications relative to when bees may have been actively foraging, since those incidents have not been formally reported to EPA and/or investigated by state lead agencies responsible for enforcing compliance with pesticide label restrictions.) Although the EIS contains numerous bee kill incident reports from beekeepers who were not providing contracted pollination services at the time of the incident, those individual reports have not been of similar magnitude (*i.e.*, simultaneously impacting thousands of hives) as those reported by commercial beekeepers providing contracted pollinator services.

When managed bees are not providing pollination services at a site that is being treated with a pesticide, they may still be directly exposed because the application site is within forage range of those bees. In such circumstances, EPA considers the likelihood of exposure to large numbers of managed bees to be somewhat lower since large numbers of colonies are not intentionally placed within or near the treatment area. EPA believes that the likelihood of exposure between the two scenarios is significantly different and that, given their proximity to the treated crop, large numbers of managed bees under contract pollination services are nearly certain to be exposed and potentially adversely affected if an application with an acutely toxic pesticide is made. Further, in evaluating these two scenarios (where bees are brought on site under contract vs. when bees may be present but the grower may not derive a benefit from the presence of bees on his or her property), EPA believes it is also appropriate to consider the benefit or lack of benefit that bees are providing to the grower in determining the nature and scope of mitigation. Consequently, EPA is proposing different mitigation approaches for these two scenarios; however, EPA will continue to evaluate the efficacy of these efforts to determine whether additional action is needed.

The proposed restrictions outlined in the following sections would not replace more restrictive chemical-specific, bee-protective provisions (*e.g.*, pre-bloom restrictions) that may already be on a product label. For example, based on chemical-specific assessment, EPA may have determined that the persistence of toxic residues in pollen and nectar requires that an application be prohibited for a period of time prior to bloom, in addition to prohibitions during bloom, in order to ensure that residues in pollen and nectar be below levels of concern when bees are likely to be exposed (*i.e.*, a pre-bloom restriction). These more restrictive prohibitions would not be superseded by the proposed mitigation described below. As discussed previously, EPA will continue to conduct comprehensive chemical-specific risk evaluations and take appropriate action to further mitigate identified risks through the registration and registration review programs based on the available science.

5.2 Application to sites with bees present under contract for pollination services

As discussed above, contracted pollination services result in a heightened exposure potential where a large number of honey bee colonies are intentionally placed at a use site, and the application of a toxic pesticide in this scenario is nearly certain to result in adverse effects to pollinators. Although the likely outcomes are counter-productive for both the beekeeper (loss of honey bee stock) and the grower (diminished pollination services), many beekeepers and growers have not found ways to avoid such outcomes. Consequently, EPA believes that strong regulatory measures should be in place for the contracted service scenario to mitigate these potential problems. Therefore, EPA proposes the following:

- To prohibit the foliar application of acutely toxic products during bloom for sites with bees on-site under contract, unless the application is made in accordance with a government-declared public health response. (See proposed label language in **Appendix B.**)

There would be no other exceptions to the bloom prohibition in the contracted-services scenario. Current neonicotinoid product labels include a 48-hr notification exception to the bloom prohibition. However, as part of this mitigation proposal, the 48-hr notification exception for crops under contracted pollination services during bloom for all neonicotinoid product labels would be removed.

The proposed mitigation applies to all products (FIFRA Section 3 and 24(c) Special Local Need registrations and where applicable Section 18 emergency exemption petitions*) that have:

- (1) liquid or dust formulations as applied; and,
- (2) foliar use directions for use on agricultural crops with bees onsite under contract for pollination services; and,
- (3) active ingredient(s) that have been determined via testing to have an acute contact toxicity value less than 11 micrograms per bee ($LD_{50} < 11 \mu\text{g}/\text{bee}$). The active ingredients that meet this criterion are listed in Appendix A. EPA will also consider as a line of evidence those active ingredients that have resulted in bee kill incidents that were investigated and determined to result from the proper use (*i.e.*, were not the result of a misuse) of a product.

*depending on the nature of the emergency for which a Section 18 petition has been submitted, the at-bloom restriction may not apply. This determination will be reached on a case-by-case evaluation.

The mitigation measures proposed for when bees are present under contract pollination would not apply to applications made in support of public health such as use for wide area mosquito control. EPA recognizes that a wide area mosquito control application can impact large numbers of bees if the application co-occurs in areas with pollinator-attractive plants; however, such applications utilizing products classified as acutely toxic to bees are used to protect public health through mosquito abatement.

Also, EPA encourages pollination service contracts established between growers and beekeepers that take into account the increased likelihood of bee colony exposure by including provisions to ensure that colonies will be protected and pollination services secured. If EPA receives evidence during the public comment period and/or through outreach at stakeholder meetings that such contract provisions are common or that there are other effective and mutually agreed upon stakeholder (*i.e.*, beekeeper-to-grower) practices indicating that application of acutely toxic pesticides is not of risk concern for bees under contract, then EPA will consider this evidence in determining whether this scenario needs the mitigation indicated in the proposed language.

5.3 Application to sites that are not under contracted pollination services

EPA believes that managed bees not under contracted services (and other unmanaged bees) may also be exposed to acutely toxic pesticides when they are within forage range of the application site. While pesticide exposure under this scenario is possible, it is less certain than in situations where a pesticide is applied to a site when large numbers of managed bees have intentionally been positioned at the site for the purposes of providing pollination services. EPA believes that the lower likelihood of exposure for large numbers of managed bees in this scenario may warrant, in the future, a more flexible approach toward mitigation such as that afforded by state or tribal Managed Pollinator Protection Plans (MP³s). Further, feedback provided by multiple stakeholders (including growers, applicators, beekeepers, and state lead agencies) indicates that there is a wide range of local conditions which militate against a single regulatory approach to providing protections for non-contracted managed bees. Many, however, have recognized that the success of pollinator protection efforts will depend on clear communication among affected stakeholders to design effective, localized approaches.

Accordingly, EPA will encourage states and tribes to develop MP³s that are effective in reducing the likelihood of bees being present in the treatment area at the time a pesticide application is to be made. EPA will work with state and tribal lead agencies to facilitate adoption of and compliance with MP³s that reflect local agronomic practices. This can be best achieved through state or tribal MP³s which results from a public stakeholder process. EPA will monitor success of these MP³s in mitigating risk to bees from acutely toxic pesticides on an ongoing basis and determine whether additional EPA action is warranted. Therefore, for managed bees not under contact pollination services, no further changes to product labels, including the neonicotinoid pesticides, are proposed at this time.

5.3.1 State and Tribal Managed Pollinator Protection Plans (MP³s)

Through discussions with the PPDC, AAPCO, and SFIREG, EPA recognizes that several states (*e.g.*, California⁴³ ⁴⁴, Colorado⁴⁵, Florida⁴⁶, Mississippi⁴⁷, and North Dakota⁴⁸) have developed MP³s by productively engaging stakeholders within their respective states. These plans serve as examples of effective collaboration between stakeholders at the local level that can lead to broader awareness of needs and increased cooperation between stakeholders to reduce pesticide exposure for bees while maintaining the flexibility to protect crops. The common element in these plans has been the increased communication between stakeholders, and anecdotal reports from the stakeholder groups suggest that the plans are effective at increasing communication and cooperation.

The EPA is generally promoting the development of state and tribal MP³s that cover use of acutely toxic pesticides sites where there are no bees onsite under contract pollination services; however, the scope of such plans is not limited to a specific scenario. States and tribes have the flexibility to determine the scope of an MP³ that best responds to pollinator issues in their region. For example, the scope could include applications to crops, and commercial applications to ornamentals in commercial, public, and residential settings, and other scenarios.

SFIREG has drafted guidance for states to consider in developing MP³s, which identifies several elements for establishing a framework for communication and cooperation between beekeepers and growers and reducing pesticide exposure for managed bees. Tribes are also encouraged to consider this guidance in developing their own MP³s, as appropriate. In general, these elements include a public stakeholder participation process for the development of a MP³ to encourage local solutions based on improved communication and cooperation; a method for growers/applicators to know if there are managed bees near treatment sites, and to identify and contact beekeepers prior to application that will enable the grower/applicator to communicate about any planned treatments and how best to protect the colonies; inclusion of best management practices that both the grower/applicator and beekeeper can undertake to limit exposure of the managed bees to the proposed pesticide application; a clear defined plan for public outreach to promote robust adoption of the plan; a process to periodically review and modify the plan as needed; and a mechanism to measure the effectiveness of the managed pollinator protection plan. In addition, other recommendations are included in the guidance document for consideration in developing MP³s. This draft guidance document has been circulated by SFIREG for wider review by states and is, therefore, subject to change. The final guidance document is expected to be made available following incorporation of their feedback.

While EPA's proposed label statement would address risks to managed bees present at a site under contract for pollination services, state and tribal MP³s may address pesticide-related risks to all pollinators, including managed bees, whether or not they are present under a contract, as well as wild pollinators. As noted earlier though, the scope of state and tribal MP³s is not limited to a particular

⁴³ California Department of Food and Agriculture. 2014. Bee and Beehive Information. <http://www.cdfa.ca.gov/plant/pollinators/index.html>

⁴⁴ California Food and Agricultural Code Section 29040-29056 <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=fac&group=29001-30000&file=29040-29056>

⁴⁵ Colorado Environmental Pesticide Education Program. Pollinator Protection 2013. <http://www.cepep.colostate.edu/Pollinator%20Protection/index.html>

⁴⁶ *Ibid* Florida Department of Agriculture and Consumer Services. 2014.

⁴⁷ *Ibid* Mississippi Honeybee Stewardship Program. 2014.

⁴⁸ *Ibid* North Dakota Department of Agriculture. 2014.

scenario for managed bees nor would such plans be limited to agricultural practices but could extend to a broader number of pollinating species and habitats. EPA has worked collaboratively with the U.S. Department of Agriculture and Michigan State University, as well as consulted published sources^{49 50 51}, to identify plants that are pollinator attractive and which require managed pollination services. The list of pollinator-attractive plants is based in part on those plants contained in the European Food Safety Authority (EFSA) guidance for assessing risks of pesticides to bees⁵²; however, USDA has included a broader number of plant species in its assessment and has provided references to support the attractiveness classification. Based on the list, most crops categorized as attractive to native bees are attractive to honey bees as well; EPA recognizes that there are exceptions (*e.g.*, tomatoes). States and tribes are encouraged to consider this list of pollinator-attractive plants when it becomes available for developing their MP³s.

6 Uncertainties

While the intent of the proposed label changes and state and tribal MP³s is to reduce exposure of managed bees to pesticides that are acutely toxic on contact, uncertainties remain regarding chemicals that may not fall within the domain of the proposal. These uncertainties are discussed below.

6.1 Non-acutely toxic insecticides and insect growth regulators

EPA recognizes that in addition to causing acute lethal effects, pesticides may cause sublethal chronic effects and effects to insect pollinators at various life stages and at various levels of biological organization (individual and colony-level). Specifically, non-acutely toxic insecticides such as insect growth regulators (IGRs) generally target early developmental stages (*e.g.*, larvae, pupae) and have varying degrees of specificity to target pest species. The determination of whether or not a specific IGR will have activity on honey bees and non-*Apis* pollinator species needs to be made on a chemical-specific basis. For example, EPA has a full suite of effects data for methoxyfenozide, a chemical which mimics the molting hormone ecdysone, and these data show that the chemical does not adversely affect larval and adult honey bees, either at the individual level or at the whole colony level. However, there are preliminary data for other IGRs (*e.g.*, diflubenzuron) which suggest possible adverse effects to honey bee larval and pupal development. As discussed previously, to address these concerns, EPA will continue to require a suite of effects and residue studies, conduct comprehensive chemical-specific risk evaluations according to the *Guidance for Assessing Pesticide Risks to Bees*,⁵³ and take appropriate action to further mitigate identified risks through the registration and registration review programs based on the available science.

⁴⁹ McGregor SE, 1976. Insect pollination of cultivated crop plants. Agricultural Handbook No. 496. Ed USDA Agricultural Research Service W, D.C, USA.

⁵⁰ Free JB. 1993. Insect Pollination of crops, 2nd edn. Academic Press: London, UK.

⁵¹ Delaplane, K. S. & Mayer, D. F. (2000). Crop Pollination by Bees. – New York, Oxon (CABI Publishing).

⁵² European Food Safety Authority, 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). Appendix D. EFSA Journal 2013; 11(7):3295, 266 pp., doi: 10.2903/j.efsa.2013.3295.

⁵³ *ibid* USEPA 2014

6.2 Insect Growth Regulators and Fungicide Tank Mixes

EPA is also aware of concerns regarding the potential effects to honey bee larvae and queen development reported in connection with bee incidents following tank mixed applications of certain fungicides with insecticides (including IGRs that are not acutely toxic to adult bees). Field reports from beekeepers allege that applications of these tank mixes during almond bloom are having colony-level effects. However, there are also beekeepers reporting little to no effects on bees located close to the sites of tank-mixed applications in question. Additionally, EPA is aware of research that is being conducted to quantify the level of interaction between some IGRs and some fungicides^{54 55}. The research to date is limited and specific to diflubenzuron (Dimilin®) and a subset of fungicides (*e.g.*, boscalid and pyraclostrobin (Pristine®)), but this research has shown no synergistic effects at environmentally relevant concentrations. Additional research to evaluate the interaction between Dimilin® and other fungicides (*e.g.*, propiconazole, Tilt® and iprodione, Roval®) and other IGRs (*e.g.*, methoxyfenozide, Intrepid®) at environmentally relevant concentrations is underway⁵⁶. EPA will continue to evaluate the open literature as part of the registration and registration review programs and may require additional testing on specific IGR-fungicide combinations to address specific uncertainties identified in the open literature and through reported incidents. Additionally, EPA requests that additional scientific information regarding the effects of tank-mixed IGRs and fungicides be submitted in response to this proposal.

6.3 Systemic Pesticides and Prolonged Residual Toxicity

EPA recognizes the concern surrounding systemic pesticides and those with prolonged residual toxicity. Systemic pesticides that have prolonged residual toxicity may not be adequately addressed by the proposed mitigation discussed in this proposal. When applied using methods other than foliar treatments (*e.g.*, soil, seed treatment, and tree injection applications), systemic pesticides and/or pesticides with prolonged residual toxicity may result in residues in pollen and nectar at levels that can impact bees and hive health. However, the likelihood of this occurring is highly dependent on the specific properties of the pesticide (*i.e.*, the degree to which the pesticide is transported in the plant, the persistence of the pesticide residues, and the levels at which lethal and non-lethal effects occur). As discussed previously, to address these concerns, EPA will continue to require a suite of effects and residue studies, conduct comprehensive chemical-specific risk evaluations according to the Guidance for Assessing Pesticide Risks to Bees⁵⁷, and take appropriate action to further mitigate identified risks through the registration and registration review programs based on the available science.

6.4 Indeterminate Bloom

EPA understands that there are some flowering crops and ornamentals that have an indeterminate period of bloom, *i.e.*, these crops flower, set fruit and continue to flower throughout the year, and that for these crops bees are present under contract for pollination services for extended periods of time. Examples of indeterminate blooming crops which involve commercial pollination services include: cucurbits, strawberries, *etc.* EPA recognizes that the proposed prohibition on application of acutely toxic pesticides during the time when bees are present under contract may cause significant issues for

⁵⁴ DeGrandi-Hoffmann, G., Y. Chen and R. Simonds. 2013. The Effects of Pesticides on Queen Rearing and Virus Titers in Honey Bees (*Apis mellifera* L.). *Insects* 4(1): 71 – 89 doi 10.3390/insects4010071

⁵⁵ Johnson, R. M. and E. Percel. 2012. Pristine Effects on Queen Rearing Process. Final report to Project Apis m.

⁵⁶ Johnson, R.M., E.G. Purcell. 2013. "Effect of 'Bee-Safe' Insecticides and Fungicides on Honey Bee Queen Development and Survival." Poster presented at 2nd International Conference on Pollinator Biology, Health and Policy, Aug. 14–17, 2013, Pennsylvania State University.

⁵⁷ *Ibid* USEPA 2014

the growers of these crops. Therefore, EPA requests input during the comment period on alternative mitigation approaches for these pollinator-attractive crops with indeterminate periods of bloom.

6.5 Microbial Pesticides

EPA recognizes that microbial pesticide toxicity values are not typically expressed in terms of micrograms per bee or determined from contact exposure which is typically seen with conventional pesticides. However, the mitigation measures/approach described in this proposal may be appropriate for microbial products that are acutely toxic or pathogenic to bees. Before determining whether mitigation would be appropriate for any microbial pesticide, EPA would need to evaluate whether the honeybee toxicity/pathogenicity studies it receives for microbial pesticides can yield some equivalent information about acute toxicity that is presented by the contact toxicity tests done for conventional chemicals. If not, EPA would need to determine whether additional data are needed to more fully evaluate microbial pesticides' risks to bees, and what regulatory triggers are appropriate for determining the need for this proposed mitigation. These data and resulting triggers might vary based on factors such as the type of microbial pesticide (e.g., insect pathogens, live microbes, killed microbes) and expected routes of exposure.

7 Implementation

Proposed label language that reflect the prohibition of foliar application of acutely toxic products during bloom for sites with bees on-site under contract is provided in Appendix B. Instructions to registrants are to be developed that will describe the specific changes that are to be made to product labels that are consistent with these changes, including the select neonicotinoid products labels that were previously modified to reduce risks to bees.

8 Summary

As discussed in this paper and consistent with previous actions by the EPA and the Strategy, EPA is proposing additional restrictions for pesticide applications to blooming crops where managed bees are present under a contract, for pesticides that are acutely toxic to bees (*i.e.*, those chemicals with an acute contact $LD_{50} < 11 \mu\text{g}/\text{bee}$). For applications of acutely toxic pesticides at bloom where bees may be present other than from contracted pollination, EPA is expecting the development of state and tribal managed MP³s contoured to reflect local needs and conditions to address exposure of managed bees in non-contracted scenarios. EPA will be evaluating on an ongoing basis the effectiveness of these plans at reducing exposure of bees to pesticides. After state or tribal MP³s have been in place for several years, EPA will then determine whether additional label revisions are appropriate. These actions are intended to reduce the likelihood of acute exposure of honey bees following application of acutely toxic pesticides. In being protective for managed honey bees, these actions are believed to be protective for other solitary and social bees and other pollinators that may be at or near the application site at bloom.

The Agency has relied on multiple lines of evidence (*e.g.*, acute toxicity studies as well as bee kill incident data when available) to support its understanding of the acute exposure to and toxicity of the pesticides in question. The proposed mandatory language in the Directions for Use is based on the available science and the expectation that larger numbers of bees will be present in or near application sites under contracted pollination services. The proposed mitigation is intended to enhance pollinator protection for particular application scenarios and is not intended to supersede more restrictive

product-specific use prohibitions. Through both the registration and registration review programs, EPA will continue to conduct chemical-specific risk assessment for bees that will address other potential routes of exposure (*e.g.*, ingestion of pesticide residues in pollen and nectar) and other potential effects (*e.g.*, chronic effects) and will consider additional, appropriate product-specific mitigation as needed.

Appendix A – List of registered active ingredients that meet the acute toxicity criteria

Abamectin	Dicrotophos	Momfluorothrin
Acephate	Dimethoate	Naled
Acetamiprid	Dinotefuran	Oxamyl
Aldicarb	Diuron	Permethrin
Alpha-cypermethrin	D-trans-allethrin	Phenothrin
Amitraz	Emamectin benzoate	Phorate
Arsenic acid	Endosulfan	Phosmet
Azadirachtin	Esfenvalerate	Pirimiphos-methyl
Bensulide	Ethoprop	Prallethrin
Beta-cyfluthrin	Etofenprox	Profenofos
Bifentazate	Fenazaquin	Propoxur
Bifenthrin	Fenitrothion	Pyrethrins
Carbaryl	Fenpropathrin	Pyridaben
Carbofuran	Fipronil	Resmethrin
Chlorethoxyfos	Fluvalinate	Rotenone
Chlorfenapyr	Fosthiazate	Sethoxydim
Chlorpyrifos	Gamma-cyhalothrin	Spinetoram
Chlorpyrifos methyl	Imidacloprid	Spinosad
Clothianidin	Imiprothrin	Sulfoxaflor
Cyantraniliprole	Indoxacarb	Tefluthrin
Cyfluthrin	Lambda-cyhalothrin	Tetrachlorvinphos
Cypermethrin	Malathion	Tetramethrin
Cyphenothrin	Metaflumizone	Thiamethoxam
Deltamethrin	Methiocarb	Tolfenpyrad
Diazinon	Methomyl	Zeta-cypermethrin
Dichlorvos		

Appendix B – Proposed Labeling

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR FOLIAR APPLICATIONS OF THIS PRODUCT TO SITES WITH BEES ON-SITE FOR COMMERCIAL POLLINATION SERVICES: Foliar application of this product is prohibited from onset of flowering until flowering is complete when bees are on-site under contract, unless the application is made in association with a government-declared public health response. If site-specific pollinator protection/pre-bloom restrictions exist, then those restrictions must also be followed.